REMARKS/ARGUMENTS

Applicant respectfully requests reconsideration of this application. By the amendments, Applicant does not acquiesce to the propriety of any of the Office's rejections and do not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In the Specification

The specification was objected to because the description of Figures 10-12 (paragraphs [0032] - [0034]) lacked reference to portions of the figures. Paragraphs [0032] - [0034] have been amended to recite that the indicated domain is "indicated in the hatched portion of the molecule as suggested by the Office.

The specification has further been objected to because paragraph [0038] does not refer to both panels of Figure 16. Paragraph [0038] has been amended to recite that FIG. 16A depicts treated mice and FIG. 16B depicts control mice.

No new matter has been introduced as a result of the claim amendments.

In the Claims

Claims 1-5 are pending in this application.

Claim 1 has been amended to clarify that step (f) comprises determined the presence of DC or AReg in the differentiated cell population. Furthermore a final step has been added which recites "wherein the relative presence of DCs and/or AReg identifies an immunosuppressive NICE or an immunostimulatory NICE." Support for the amendment to claim 1 can be found at least in paragraphs **[0058]** and **[0059]** of the published application.

No new matter has been introduced as a result of the claim amendments.

35 U.S.C. §112 Rejections

Claims 1-5 have been rejected under 35 USC §112, second paragraph, as being incomplete for omitting essential step.

Applicant has amended claim 1 to recite the step ""wherein the relative presence of DCs and/or AReg identifies an immunosuppressive NICE or an immunostimulatory NICE."

Therefore, Applicant requests the withdrawal of the rejection on this basis.

35 U.S.C. §103 Rejections

Claims 1-5 have been rejected under 35 USC §103(a) as allegedly being unpatentable over Cohen (US 6,667,151; hereinafter the '151 patent) in view of Cohen et al. (hereinafter "Cohen"), Cheadle et al. (hereinafter "Cheadle) and Baghian et al. (hereinafter "Baghian). Applicant respectfully disagrees.

To maintain a proper rejection under 35 U.S.C. § 103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck,* 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak,* 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight

that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

The instant claims are drawn to a method of identifying new immunomodulatory chemical entities with either immunosuppressive or immunostimulatory activity by assaying the ability of candidates to induce monocytes to differentiate into dendritic cells (DCs) or regulatory macrophages (AReg). The claimed method requires the determination of numbers of both DCs and AReg in the test cultures.

The cited prior art only discloses measuring expression of the Fas ligand. The presence of FasL only indicates the presence of immunosuppressive AReg, and does not indicate the presence or absence of DCs (see instant specification, paragraphs [0050] for example). The claimed method includes the step of determining numbers of both DCs and AReg in the culture in order to determine if the NICE is immunosuppressive or immunostimulatory.

None of the '151 patent, Cohen, Cheadle or Baghian, either individually or in combination, teach or suggest determining the levels of both DCs and ARegs and therefore do not teach or suggest all the claim limitations. Thus, the Office has not established *prima facie* obviousness of the pending claims over the '151 patent in view of Cohen, Cheadle and Baghian and Applicant respectfully requests withdrawal of the rejection on this basis.

CONCLUSION

In light of the claim amendments and arguments presented *supra*, Applicant respectfully asserts that the pending claims are in condition for allowance and requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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